DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. 01D–0294 and 01D–0295]

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Providing Regulatory Submissions in Electronic Format for Food Additive and Color Additive Petitions

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that the proposed collection of information listed below has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments on the collection of information by [*insert date 30 days after date of publication in the* **Federal Register**].

ADDRESSES: Submit written comments on the collection of information to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attn: Stuart Shapiro, Desk Officer for FDA.

FOR FURTHER INFORMATION CONTACT: Peggy Schlosburg, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1223.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Providing Regulatory Submissions in Electronic Format for Food Additive and Color Additive Petitions

Section 409(a) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 348(a)) provides that a food additive shall be deemed to be unsafe unless: (1) It and its use or intended use are in conformity with a regulation prescribing the condition(s) under which such additive may safely be used; (2) it and its use or intended use conform to the terms of a regulatory exemption for investigational use; or (3) for a food contact substance, the substance and the use of such substance are in conformity with a regulation prescribing the conditions under which such additive may be safely used or a food contact notification submitted under section 409(h) of the act is effective. Individuals or companies submit food additive petitions to obtain approval of a new food additive or to amend the conditions of use permitted under an existing food additive regulation. The regulation in 21 CFR 171.1 specifies the information that a petitioner must submit in order to establish that the proposed use of a food additive is safe for its proposed use. This regulation implements section 409(b)(2) of the act.

Section 721(a) of the act (21 U.S.C. 379e(a)) provides that a color additive shall be deemed to be unsafe unless: (1) The additive and its use are in conformity with a regulation listing such additive for such use, including any provision that describes the condition(s) under which the additive may safely be used and is either batch certified for such use or exempted from the certification requirements; or (2) the additive and its use conform to the terms of an exemption for investigational use issued under section 721(f) of the act. Individuals or companies submit color additive petitions to obtain approval of a new color additive or a change in the conditions of use permitted for a color additive that is already approved. The regulation in 21 CFR 71.1 specifies the information that a petitioner must submit in order to establish that a color additive is safe and suitable for its proposed use.

Respondents to this collection of information are businesses engaged in the manufacture or sale of food, food ingredients, substances used in materials that come into contact with food or engaged in the manufacture or sale of foods, drugs, devices, or cosmetics containing color additives.

The agency estimates that up to 30 percent of the petitioners for both food and color additives will take advantage of the electronic submission process during the first year. By using the guidelines, including the forms that FDA is providing, the petitioner will be able to organize the petition to focus on the information needed to expedite review of the petition. Therefore, we estimate that petitioners will only need to spend approximately 1 hour completing the electronic submission application form (FDA Form 3503 or 3504, as appropriate) because they will have already organized the information needed for the submission into the appropriate categories.

In the **Federal Register** of July 31, 2001 (66 FR 39517), the agency requested comments on the proposed collection of information. No comments were received.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section/Part/FDA Form	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours	Total Operating and Maintenance Costs
Food additive petitions[2]—electronic submissions						
FDA Form 3503	3	1	3	1	3	0
171.1—electronic submissions	3	1	3	4,799	14,397	0
172—electronic submissions	3	1	3	0	0	0
173—electronic submissions	3	1	3	0	0	0
175 through 178—electronic submissions	3	1	3	0	0	0
180—electronic submissions	3	1	3	0	0	0
Subtotal					14,400	0
Color additive petitions[2]—electronic submissions						
FDA Form 3504	1	1	1	1	1	0
70.25—electronic submissions	0	0	0	0	0	0
71.1 category A[3]—electronic submissions	1	1	1	608	608	2,600
71.1 category B[4]—electronic submissions	1	1	1	2,394	2,394	3,000
71.1 category C[5]—electronic submissions	0	0	0	0	0	0
Subtotal					3,003	$5,600
Total					17,403	$5,600

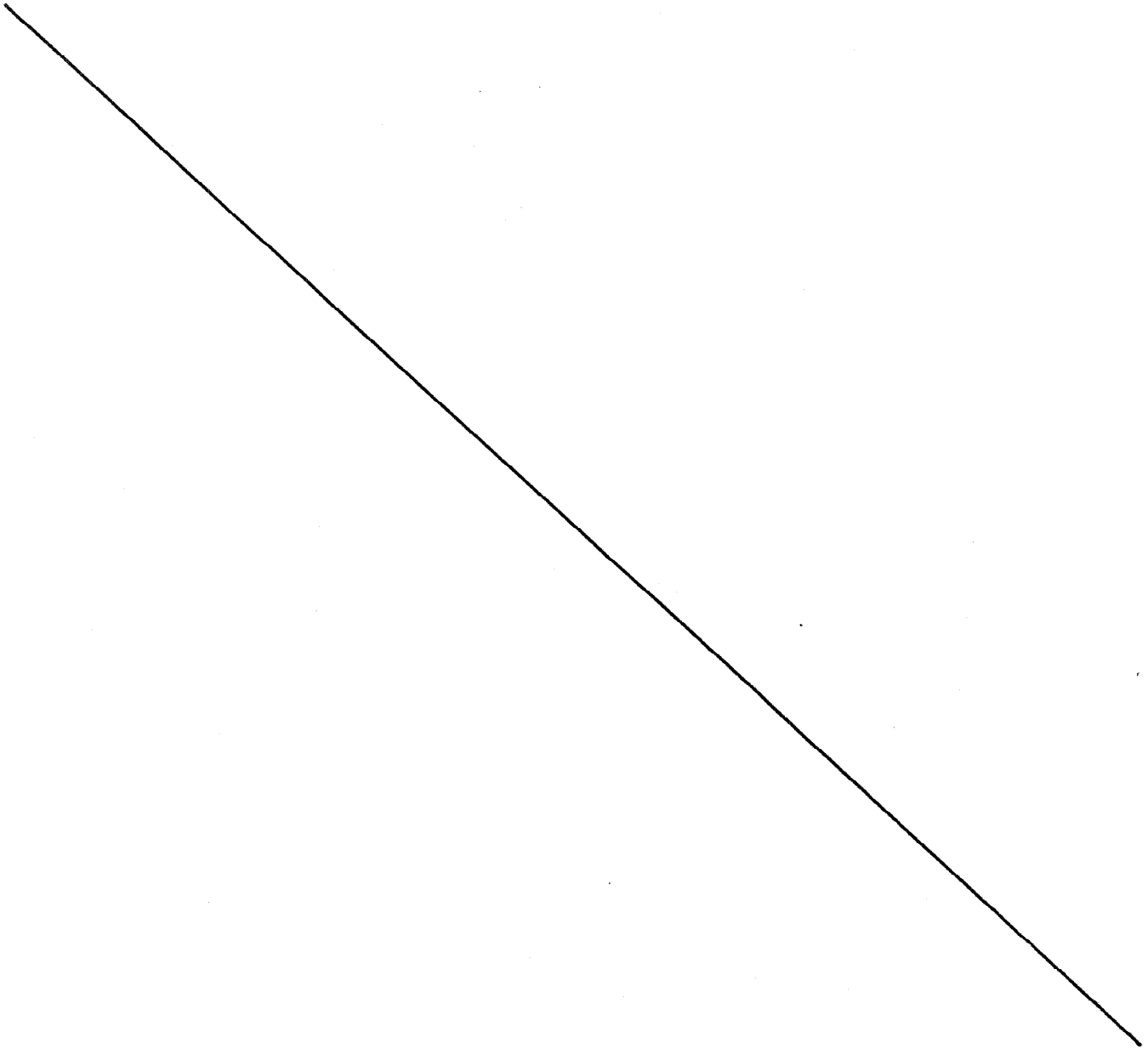
[1] There are no capital costs associated with this collection of information.
[2] The electronic submissions (e-submissions) contain the same petition information required for paper submissions; only the submission format will contain both electronic and paper.
[3] Category A—A color additive petition with minimal testing requirements, such as is typical for medical device color additive petitions (toxicity studies, collection of identity information, analytical information, and administrative details).
[4] Category B—An average color additive petition consisting of analytical work, 90-day feeding study, and the administrative details, which include the drafting of the regulations.
[5] Category C—A petition for a completely new food, drug, or cosmetic color.

Under parts 71 and 171 (21 CFR parts 71 and 171), the agency requires that the petitioner submit the petitions in triplicate. The draft guidance for industry entitled "Providing Regulatory Submissions to Office of Food Additive Safety in Electronic Format for Food Additive and Color Additive Petitions" provides that petitioner should include one copy of the petition in electronic format ("electronic copy") and one copy in paper format ("paper copy"). The submission of an electronic copy, however, is not expected to significantly increase the burden of preparing the submission because it merely serves as a substitute for paper copies. Further, the agency also plans to hold consultations with the petitioners during the time of preparation to ensure that the information that the petitioners submit meets the current requirements in parts 71 and 171 and that it is in the recommended format.

The estimate of burden for electronically submitted food additive petitions is based on the number of new food additive petitions received in fiscal year (FY) 1999 and the total hours expended by petitioners to prepare the petitions. We estimate that during the first year, the electronic submission process will reduce the total time of preparation for food additive petitions by approximately 10 percent of the burden previously estimated for paper petitions (see 65 FR 64222, October 26, 2000). Although the burden varies with the type of petition submitted, an average food additive petition involves review of appropriate scientific studies, as well as the work of drafting the petition itself. The burden varies depending on the complexity of the petition, including the amount and types of data needed for scientific analysis.

The estimate of burden for electronically submitted color additive petitions is based on an average of five new color additive petitions received each year in FY 1998 and 1999. We estimate that during the first year, the electronic submission process will reduce the total time of preparation for color additive petitions by approximately 10 percent of the burden previously estimated for paper petitions (see 64 FR 51128, September 21, 1999). Although the burden varies with the type of petition submitted, an average color additive petition involves analytical work and appropriate toxicology studies, as well as the work of drafting the petition itself.

If an average of five color additive petitions (all submissions) are expected per calendar year, and only one submission per category for categories A and B is an electronic submission, the estimated annual burden for this start-up cost would be approximately $5,600. Based on the assumption that companies will use the same equipment for generating both paper and electronic records after this initial start-up cost, i.e., software and storage media for preparing both paper



and electronic submissions, the burden of maintaining electronic equipment and of maintaining electronic records should not increase the burden of preparing such petitions. In fact, the cost of shipping electronic media should be less than shipping paper copies of petitions.

Dated: 11-26-01
November 26, 2001.

Margaret M. Dotzel,
Associate Commissioner for Policy.

[FR Doc. 01–????? Filed ??–??–01; 8:45 am]

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